

### **REMARKS/ARGUMENTS**

Claims 17-57 are pending in this Application. The Office Action mailed on December 6, 2006 included the following rejections:

1. Claims 17-52 were rejected under 35 U.S.C. § 112 first paragraph.
2. Claims 17-19, 21, 23-49, 51 and 53-57 were rejected under 35 U.S.C. § 112 first paragraph.

Applicant respectfully addresses the basis for each of the Examiner's rejections below.

***Claims 17-52 are rejected under 35 U.S.C. 112 first paragraph as failing to comply with the enablement requirement.***

The Action rejects claims 17-52 under 35 U.S.C. § 112 first paragraph, which states:

The claims contain subject matter which was not described in the specification in such a way as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

However, in order to make a rejection under 35 U.S.C. § 112 first paragraph, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention, e.g., *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) states the Examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure. Applicant submits that the specification as filed fully complies with 35 U.S.C. § 112 first paragraph. A specification that contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. No such reasonable doubt of the objective truth, or for that matter, the objective examples, is supported in the action.

The specification states that the nutritional supplements or pharmaceutical preparations having seven-carbon fatty acids are useful in treatment of inherited metabolic disorders as well

as acquired metabolic derangements, e.g., see [0069]. The specification provides an example as a preferred seven-carbon fatty acid is n-heptanoic acid, see [0070]. The skilled artisan recognizes that there are a **LIMITED** number of combinations possible for a seven-carbon fatty acid, as well as a **LIMITED** number of locations that may be modified or substituted as the structure only includes seven-carbons. Furthermore, there are a limited number of motifs that can be used to modified, substituted and/or attached to the seven carbon fatty acid. The present specification also provides considerable direction and guidance on how to practice the claimed invention, presents working examples and all of the methods needed to practice the invention were either well known in the art or disclosed in the specification (e.g., See, *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)).

The Applicant asserts that the specification as disclosed does not require undue experimentation. Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). Applicants assert that when the factors to determine undue experimentation set forth in *In re Wands* are addressed the claimed invention is enabled so that any person skilled in the art can make and use the invention without undue experimentation.

Applicant addresses the *In re Wands* factors in turn. With reference to the breadth of the claims, the claims are not overly broad (e.g., to seven carbon fatty acids) as the specification teaches the use of a select group of fatty acids as opposed to all fatty acids or different groups containing fatty acids of vastly different numbers of carbons. For example, the seven carbon fatty acids are a group of fatty acids with similar chemical properties as a group, e.g., found mainly in milk fats, have similar physical properties and interactions and so forth. Although, the fatty acid may be modified, such modifications are well known to persons of ordinary skill in the art. Additionally, the specification provides examples of disorders that may be treated with the present invention. With regard to the quantity of experimentation necessary, the present invention does not require very difficult and time consuming assay (e.g., the specification provides both in-vitro and in-vivo studies) and all necessary information is present in the

specifications or known to a person of skill in the art, e.g., the base structure and modifications and substitutions are well known to the skilled artisan. The specifications provide direction and guidance including examples and results. As mentioned prior, the state of the art is high as fatty acids has been studied for many decades and therefore the predictability of the art with regards to modifications and fatty acid characteristics is also quite high. For example, certain synthetic odd-carbon number triglycerides have been tested for use in food products as potential fatty acid sources and in the manufacture of food products. The oxidation rates of odd-chain fatty acids from C<sub>7</sub> and C<sub>9</sub> triglycerides have been examined in vitro in isolated piglet hepatocytes. (Odle, et al. 1991). "Utilization of medium-chain triglycerides by neonatal piglets: chain length of even- and odd-carbon fatty acids and apparent digestion/absorption and hepatic metabolism," *J Nutr* 121:605-614; Lin, X, et al. 1996. (see [0009]). It is not necessary for the specification to provide every modification and configuration, See, e.g., *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). Currently, those of skill in the art are PhDs, MS and MDs escalating the relative level of skill of those in the art. Given the present application the examples and guidance the claimed invention is enabled so that any person skilled in the art can make and use the invention without undue experimentation.

All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further, the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). When these factors are taken as a whole it is clear that undue experimentation is not necessary; and thus, the specification is enabled to support claims 17-52.

Furthermore, it is simply inconceivable that not a single claim in the present application is allowable based on the clear limitations found in the independent and the dependent claims. For example, specific claims (e.g., Claims 52-57, Claim 22 and Claims 26-33) that list specific fatty acids and denote the exact caloric requirements that would be provided to a patient.

As such, the specification satisfies the written description requirement under 35 U.S.C. § 112, first paragraph. Regardless, the claims have been amended to expiate prosecution. For the

reasons mentioned above, the Applicants respectfully request the Examiner withdraw the rejection under 35 U.S.C. § 112.

***Claim Rejections – Claims 17-19, 21, 23-49 and 53-57 are rejected under 35 U.S.C. 112 first paragraph as failing to comply with the written description requirement.***

The Applicant asserts that the subject matter of the claims are described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). The present specification shows possession of the claimed invention by describing the claimed invention; providing examples of the present invention (e.g., example 1 and 2); demonstrating treatments to various cell lines (e.g., [0083] The normal cell line and eleven abnormal cell lines were analyzed in groups of three...); providing actual reductions to practice (e.g., [0089] Treatment of the infant with severe neonatal translocase deficiency identified in Example 1 using triheptanoin-supplemented low fat formula was successful. Additionally, there is support for the correlation between the clinical response to triheptanoin therapy and the in vitro mass spectrometry analysis of the infant's amniocytes., [0090] At 38 weeks gestation, delivery of the infant whose amniocytes tested positive for severe translocase deficiency as described in Example 1 was accomplished.); providing specific examples of compounds (e.g., [0072] Heptanoic acid is found in various fusel oils in appreciable amounts and can be extracted by any means known in the art.); providing sources for the compound (e.g., [0072] Heptanoic acid is also commercially available through Sigma Chemical Co. (St. Louis, MO) and [0073] Triheptanoin can be obtained by the esterification of heptanoic acid and glycerol by any means known in the art. Triheptanoin is also commercially available through Condea Chemie GmbH (Witten, Germany) as Special Oil 107.); and providing an example of a compound of the present invention (e.g., [0070] A

preferred seven-carbon fatty acid is n-heptanoic acid. n-Heptanoic acid is a saturated straight chain seven-carbon fatty acid with the following structure). The skilled artisan would immediately recognize the inventor had possession of the claimed invention given the examples of the present invention.

The Action cites *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species). However, the present application provides descriptions and examples of the genus, species and further provides specific examples of some species, e.g., [0070] A preferred seven-carbon fatty acid is n-heptanoic acid. n-Heptanoic acid is a saturated straight chain seven-carbon fatty acid with the following structure; and Claim 22. disclosing specific examples of n-heptanoic acid: 4-methylhexanoate, 4-methylhexenoate, 3-hydroxy-4-methylhexanoate; 5-methylhexanoate, 5-methylhexenoate and 3-hydroxy- 5 - methylhexanoate.

In addition, there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims"). The Office has failed to establish evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims. Applicant request the Office provide such evidence or withdraw the rejection.

As such, the specification satisfies the written description requirement under 35 U.S.C. § 112, first paragraph. For the reasons mentioned above, the Applicant respectfully requests the withdrawal of the rejection under 35 U.S.C. § 112.

**Conclusion**

In light of the remarks and arguments presented above, Applicant respectfully submits that claims 17, 19-47 and 49-57 are pending in this application and claims 18 and 48 have been cancelled. Applicant submits that this application are in condition for allowance. Favorable consideration and allowance of the pending claims are therefore respectfully requested.

If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

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Respectfully submitted,



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